510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY
DEVICE ONLY TEMPLATE

A. 510(k) Number:

k032663

B. Analyte:

C-reactive protein

C. Type of Test:

Quantitative Immunoturbidimetirc Latex Agglutination

D. Applicant:

INSTRUMENTATION LABORATORY CO.

E. Proprietary and Established Names:

QUANTEX CRP HIGH SENSITIVITY, QUANTEX CRP HIGH SENSITIVITY STANDARD MULTIPOINT, QUANTEX CRP HIGH SENSITIVITY CONTROLS 1/2

F. Regulatory Information:

1. Regulation section:
   21CFR §866.5270 -C-reactive protein immunological test system.
   21CFR§862.1150 - Calibrator, primary
   21CFR§862.1660 - Single analyte controls (assayed and unassayed)
2. Classification:
   2, 2, 1
3. Product Code:
   DCK, JIS, JJX
4. Panel:
   Immunology (82), Chemistry (75)

G. Intended Use:

1. Indication(s) for use:
   Quantex CRP High Sensitivity is intended as a latex particle enhanced immunoturbidimetric assay for the quantitative determination of C-Reactive Protein (CRP) in human serum on Clinical Chemistry Systems. C-Reactive

Protein (CRP) aids in detecting and evaluating infection, tissue disorder, inflammatory disorders and associated diseases.

Quantex CRP High Sensitivity standard multipoint is intended for use in establishing the calibration for the quantex CRP High Sensitivity reagents by turbidimetry.

Quantex CRP High Sensitivity controls 1/2 are intended for use in monitoring the quality control of results obtained with quantex CRP High Sensitivity reagents by turbidimetry.

2. Special condition for use statement(s):
   Not Applicable

3. Special instrument Requirements:
   ILab 900/1800 and ILab 600

H. Device Description:

When a sample containing CRP is mixed with the Latex Reagent and the Reaction Buffer included in the kit, the coated latex particles agglutinate. The degree of agglutination is directly proportional to the concentration of CRP in the sample and is determined by measuring the decrease of transmitted light caused by the aggregates. C-Reactive Protein (CRP) aids in detecting and evaluating infection, tissue disorder, inflammatory disorders and associated diseases.

I. Substantial Equivalence Information:

1. Predicate device name(s):
   Dade Behring, N High Sensitivity CRP Assay (Predicate)

2. Predicate K number(s):
   K991385

3. Comparison with predicate:

Table of Comparison to Predicate Device

quantex CRP High Sensitivity	**N *High Sensitivity* CRP Assay (Predicate)**
Manufacturer:	
Biokit SA in Barcelona, Spain	Dade Behring in Marburg, Germany
Intended Use:	
Quantitative *in vitro* diagnostic determination of C-reactive protein	Same
Sample Type:	
Serum	Serum, Heparin and EDTA plasma
Methodology:	
Particle Enhanced Immunoturbidimetry	Particle Enhanced Immunonephelometry
Test Principle:	
When a serum containing CRP is mixed with the Latex Reagent and the Reaction Buffer included in the kit, the coated latex particles agglutinate. The degree of agglutination is directly proportional to the concentration of CRP in the sample and is determined by measuring the decrease of transmitted light caused by the aggregates.	Polystyrene particles coated with monoclonal antibodies to CRP are agglutinated when mixed with samples containing CRP. The intensity of the scattered light in the nephelometer depends on the CRP content of the sample and therefore the CRP concentration can be determined versus dilutions of a standard of a known concentration.
Storage Conditions:	
Refrigerate at 2-8°C until expired	Same
Reagent Compositions:	
• **Latex Reagent (ready-for-use)** Suspension of polystyrene latex particles coated with rabbit polyclonal antibody directed against human CRP containing bovine serum albumin, buffer and < 0.1% sodium azide.	**N High Sensitivity CRP Reagent (ready-for-use)** Suspension of polystyrene particles coated with mouse monoclonal antibodies to CRP. Preservatives Gentamincin (6.25 mg/L) and Amphotericin (0.625 mg/L).
• **Reaction Buffer (ready-for-use)** HEPES buffer containing bovine serum albumin, IgG from normal rabbit and < 0.1% sodium azide.	**No equivalent reagent**
• **quantex CRP High Sensitivity standard multipoint**	**N Rheumatology Standard SL (ready-for-use)**
• **(ready-for-use)*** Diluted normal human serum in physiological saline solution containing human CRP at 5 different levels, stabilizer and < 0.1% sodium azide.	Mixture of human sera with elevated concentration of ASL, CRP and RF. Less than 1 g/L sodium azide.
• **quantex CRP High Sensitivity controls 1/2 (ready-for-use)*** Diluted normal human serum in physiological saline solution containing human CRP at 2 different levels, stabilizer and < 0.1% sodium azide. * sold separately	**N/T Rheumatology Controls SL (ready-for-use)** Mixture of human sera with elevated concentration of ASL, CRP and RF with the additive pyrrolidine (approx. 50 g/l).

J. Standard/Guidance Document Referenced (if applicable):

None referenced

K. Test Principle:

The quantex CRP High Sensitivity is a latex particle enhanced immunoturbidimetric assay to quantify CRP in serum. When a sample containing CRP is mixed with the Latex Reagent and the Reaction Buffer included in the kit, the coated latex particles agglutinate. The degree of agglutination is directly proportional to the concentration of CRP in the sample and is determined by measuring the decrease of transmitted light caused by the aggregates.

L. Performance Characteristics (if/when applicable):

1. Analytical performance:
   a. Precision/Reproducibility:

ILab 600	Replicates/ Runs	Mean (mg/L)	CV (%)	Replicates/ Runs	Mean (mg/L)	CV (%)
Within run	6/10	2.32	2.11	6/10	5.82	1.96
Total	6/10	2.32	2.50	6/10	5.82	2.09
ILab 900/1800	Replicates/ Runs	Mean (mg/L)	CV (%)	Replicates/ Runs	Mean (mg/L)	CV (%)
Within run	6/12	2.39	1.25	6/12	5.87	0.88
Total	6/12	2.39	3.32	6/12	5.87	1.50

   b. Linearity/assay reportable range:
   ILab 600: 0.25 to 20.0 mg/L without the ILab automatic rerun capability. 0.10 to 400 mg/L with the ILab automatic rerun capability.
   ILab 900/1800: 0.35 to 20.0 mg/L without the ILab automatic rerun capability. 0.10 to 100 mg/L with the ILab automatic rerun capability.

   If the linear range is exceeded after the automatic rerun, dilute the sample 1:51 with saline, re-assay and correct the result for the dilution.

   The assay does not show prozone effect (i.e. antigen excess) up to 400 mg/L.
   c. Traceability (controls, calibrators, or method):
   The reported values were determined over multiple runs against a Calibration House Standard which is traceable to the current Certified Reference Material for human serum proteins from the Institute for Reference Materials and Measurements (IRMM)
   d. Detection limit:
   The detection limit of this assay is
   • ILab 600: 0.139 mg/L (rerun disabled); 0.046 mg/L (rerun enabled)
   • ILab 900/1800: 0.145 mg/L (rerun disabled); 0.081 mg/L (rerun enabled)

Lowest measurable CRP value with CV < 15%:
- ILab 600: 0.25 mg/L (rerun disabled); 0.10 mg/L (rerun enabled)
- ILab 900/1800: 0.35 mg/L (rerun disabled); 0.10 mg/L (rerun enabled)

e. Analytical specificity:
No significant interference from triglyceride up to 1327 mg/dL, bilirubin up to 18.3 mg/dL (311.1 µmol/L), hemoglobin up to 490 mg/dL (0.294 mmol/L), Rheumatoid Factor up to 970 IU/mL and turbidity up to a sample absorbance of 2.39 AU/cm at 660 nm.

f. Assay cut-off:
Not Applicable

2. Comparison studies:
   a. Method comparison with predicate device:
   In method comparison studies evaluating 156 samples with CRP levels ranging from 0.18 to 283 mg/L on an ILab 900/1800 and 55 samples ranging from 0.20 to 283 mg/L on an ILab 600, the slope and correlation coefficient (r) for quantex CRP High Sensitivity versus the predicate device are shown below:

IL System	Slope	Intercept	r
ILab 900/1800	0.948	-0.105	0.9969
ILab 600	0.957	-0.074	0.9989

   b. Matrix comparison:
   Not Applicable
3. Clinical studies:
   a. Clinical sensitivity:
   Not Applicable
   b. Clinical specificity:
   Not Applicable
4. Clinical cut-off:
   Not Applicable
5. Expected values/Reference range:
   A normal range study (51 Men / 68 Women; age range: 19-66) was performed using quantex CRP High Sensitivity on an ILab 900 instrument. The upper limit of the normal range, calculated as recommended by the International Federation of Clinical Chemistry (IFCC), was 5.6 mg/L (n=119), which agreed with already published values for adult population.

   Due to many variables which may affect results, each laboratory should establish its own normal range. A CRP value within the normal range does not exclude tissue damage.

M. Conclusion:

The information and data provided by INSTRUMENTATION LABORATORY CO. supports a Substantial Equivalence (SE) determination of QUANTEX CRP HIGH SENSITIVITY, QUANTEX CRP HIGH SENSITIVITY STANDARD MULTIPOINT, QUANTEX CRP HIGH SENSITIVITY CONTROLS 1/2 to other C-REACTIVE PROTEIN, ANTIGEN, ANTISERUM, AND CONTROL regulated under 21 CFR §866.5270 - C-reactive protein immunological test system.